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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,843	Applicant(s) PEI et al.	
	Examiner Brenda Coleman	Art Unit 1624	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Mar 20, 2003</u> .			
2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-30</u> is/are pending in the application.			
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>1-30</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
*See the attached detailed Office action for a list of the certified copies not received.			
14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		6) <input type="checkbox"/> Other: _____	

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DETAILED ACTION

Claims 1-30 are pending in the application.

This action is in response to applicants' amendment dated March 20, 2003. Claims 1-11, 13, 16-26 and 28 have been amended.

The amendment to claims 17 and 19 has not been entered see 37 CFR § 1.121.

Note: The applicants' are reminded of the manner of making amendments.

37 CFR 1.121. Manner of making amendments in application.

(c) Claims. —

(1) Amendment by rewriting, directions to cancel or add . Amendments to a claim must be made by rewriting such claim with all changes (e.g, additions, deletions, modifications) included. The rewriting of a claim (with the same number) will be construed as directing the cancellation of the previous version of that claim. A claim may also be canceled by an instruction.

(i) **A rewritten or newly added claim must be in clean form, that is, without markings to indicate the changes that have been made.** A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added (e.g., "amended, " "twice amended, " or "new ").

(ii) If a claim is amended by rewriting such claim with the same number, the amendment must be accompanied by another version of the rewritten claim, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of that claim. A parenthetical expression should follow the claim number indicating the status of the claim, e.g., "amended," "twice amended, " etc. The parenthetical expression "amended, " "twice amended, " etc. should be the same for both the clean version of the claim under paragraph (c)(1)(i) of this section and the marked up version under this paragraph. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled.

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(2) A claim canceled by amendment (deleted in its entirety) may be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

(3) A clean version of the entire set of pending claims may be submitted in a single amendment paper. Such a submission shall be construed as directing the cancellation of all previous versions of any pending claims. A marked up version is required only for claims being changed by the current amendment (see paragraph (c)(1)(ii) of this section). Any claim not accompanied by a marked up version will constitute an assertion that it has not been changed relative to the immediate prior version.

Response to Arguments

Applicants' arguments filed March 20, 2003 have been fully considered with the following effect:

1. With regards to the 35 USC § 112, first paragraph rejection of claims 3, 4, 6-15, 18, 19 and 31-30 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that "the claims are not drawn to the treatment of any neurodiseases, but rather, only the disorders associated with excessive activation of the AMPA subtype of the ionotropic EAA receptors". There is no evidence of record that Applicants' compounds have shown clinical efficacy for every disorder claimed herein. There is no evidence of record that any glutamatergic transmission inhibitor, of any structure, has shown clinical efficacy against the neurological diseases urged by the applicants. Thus, such compounds are not art-recognized as being useful for such purposes. Thus, there is no evidence that as of the filing date, Applicants compounds were known to be useful for such purposes. Solymon states "that 8-methoxy and 8-halogen atom substituted 2,3-benzodiazepines, 25 and 26 (Chart (3))

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respectively, also have considerable AMPA antagonist potency.” “However applying these substituents as a 7-substitution alone results in nearly inactive compounds.” See Table 4 on page 920, compound no. 25a.

There is no basis for the treatment of the asserted diseases and/or disorders in the specification, nor is there any testing to indicate that the compounds of the instant invention are effective in the treatment of the asserted diseases and/or disorders. Solyom et al. (Current Pharmaceutical Designs) states that “the efficacy of 2,3-benzodiazepine AMPA antagonists in these models points to their utility in the treatment of acute neurodegenerative diseases such as brain ischemia, stroke, and brain or spinal cord trauma”. Glutamatergic transmission is carried out by the glutamate receptors. Glutamate elicits its effects at a variety of receptors and these can be broadly classified into the ionotropic glutamate receptors (iGluRs) and the metabotropic glutamate receptors (mGluRs). The ionotropic glutamate receptors are ligand-gated, cation-permeable channels and they may be further classified, according to their selective agonists, into the NMDA and AMPA/kainate receptors. Solyom further discusses the possible pathological roles of AMPA antagonists on page 934. “The potential role of AMPA antagonists in the treatment of chronic neurodegenerative disorders is less clear.” “The pathogenesis of diseases such as Parkinson’s disease, Alzheimer’s disease and amyotrophic lateral sclerosis probably also involves excitotoxic mechanisms.” “Other potential clinical targets of 2,3-benzodiazepine AMPA antagonists include muscle spasticity and chronic (neuropathic and inflammatory) pain.” “Non-competitive AMPA antagonists may also be useful in treating schizophrenia, migraine and drug

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withdrawal symptoms.” Postulated does rise to the level of proof required for disease therapy claims.

Claims 3, 4, 6-15, 18, 19 and 21-30 (claim 28 which was inadvertently omitted in the last office action) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

2. The applicant’s amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), b), c), d), e), f), g), i), l), m), n), o), p), q), r), s), v), w), x), z), aa), ad), ae), af), ag), ah), ai), aj), an) and ao) of the last office action, which are hereby withdrawn. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled h), j), k), t), u), y), ab), ac), ak), al), and am) of the last office action, the applicant’s amendments and remarks have been fully considered but they are not persuasive.

h) The applicants’ stated that the “claims are drawn to providing compositions having a compound of formula I or formula II defined therein and methods of using the compositions for treating disorders associated with an excessive excitation of the activity of AMPA subtype of the ionotropic EAA receptors” and “claims are not limited to the treatment of any particular type neurodiseases but all of the diseases associated with an excessive excitation of the activity of AMPA subtype of the

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ionotropic EAA receptors". However, as pointed out in the response to the 112, first paragraph rejection above, a recent journal article indicates that only "the efficacy of 2,3-benzodiazepine AMPA antagonists in these models points to their utility in the treatment of acute neurodegenerative diseases such as brain ischemia, stroke, and brain or spinal cord trauma".

Claims 3, 4, 6-15, 18, 19 and 21-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

j and k) The applicants' stated that the "claims as originally filed have antecedent basis for 7-amino or 8-amino in that R¹, R², R³, and R⁴ can be R¹⁵R¹⁶N-". However, claim 5 which is dependent upon claim 2 lacks antecedent basis in that the definition of R¹, R², R³, and R⁴ fails to include R¹⁵R¹⁶N-.

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

t and u) The applicants' stated that the "claims as originally filed have antecedent basis for 7-amino or 8-amino in that R¹, R², R³, and R⁴ can be R¹⁵R¹⁶N-". However, claim 13 which is dependent upon claim 11 lacks antecedent basis in that the definition of R¹, R², R³, and R⁴ fails to include R¹⁵R¹⁶N-.

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Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- y) The applicants' stated that the "claims are amended to recite "R¹⁴S-," which is included in the definition of claim 16, as amended". However, claim 17 which is dependent upon claim 16 lacks antecedent basis in that the definition of R¹, R², R³, and R⁴ was not amended, that is R¹³S- is still present in the definition.

Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- ab and ac) The applicants' stated that the "claims as originally filed have antecedent basis for 7-amino or 8-amino in that R¹, R², R³, and R⁴ can be R¹⁵R¹⁶N-". However, claim 20 which is dependent upon claim 17 lacks antecedent basis in that the definition of R¹, R², R³, and R⁴ fails to include R¹⁵R¹⁶N-.

Claim 20 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- ak) The applicants' stated that the "claims are amended to recite "R¹⁴S-," which is included in the definition of claim 25, as amended". However, claim 26 which is

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dependent upon claim 25 lacks antecedent basis in that the definition of R¹, R², R³, and R⁴ was not amended, that is R¹³S- is still present in the definition.

Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

al and am) The applicants' stated that the "claims as originally filed have antecedent basis for 7-amino or 8-amino in that R¹, R², R³, and R⁴ can be R¹⁵R¹⁶N-". However, claim 28 which is dependent upon claim 26 lacks antecedent basis in that the definition of R¹, R², R³, and R⁴ fails to include R¹⁵R¹⁶N-.

Claim 28 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 16-19, 23 and 24 labeled paragraph 3 in the last office action which is hereby **withdrawn**.

4. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 16-19, 23-27 and 30 labeled paragraph 4 in the last office action which is hereby **withdrawn**.

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5. With regards to the 35 U.S.C. § 102, anticipation rejection of claims 1-30 labeled paragraph 5 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. Ling et al., WO 97/28135 (U.S. equivalent 6,200,970), teaches the compounds, compositions and method of use of the instant invention where R¹ is hydrogen, R² is methoxy, R³ is hydrogen, bromo or chloro, R⁴ is hydrogen, R⁵ is hydrogen, R⁶ is hydrogen, R⁷ is methyl, R⁸ is hydrogen, R⁹ is C(=O)CH₃, C(=O)NHCH₃, C(=O)CH₂CH₃, C(=O)cyclopropyl, C(=O)OCH₃, R¹⁰ is NH₂, R¹¹ is hydrogen and R¹² is hydrogen for Formula I and R¹⁸ is hydrogen, R¹⁹ is hydrogen, R²⁰ is NH₂, and R²¹ is hydrogen for Formula II. See the printout of the species within the disclosure of WO 97/28135. The applicants' stated that "the structure at p. 1 requires an un-saturation in the diazepine ring of the structure (represented by the dash line covering the 3-, 4- and 5-positions of the diazepine ring)" and "therefore, the generic structure of Ling does not encompass compounds which do not have an un-saturation in the 3-, 4-, and 5-positions of the diazepine ring". However, the disclosure of Ling is such that the dotted lines means a double bond or single bond.

The applicants' also stated that "claims 1-30 are drawn to 5H-2,3-benzodiazepine or 3,5-dihydro-5H-2,3-benzodiazepine compounds, compositions forming of the compounds or methods of using the compositions and/or compounds". However, as pointed out in the HCAPLUS printout herein provided, the nomenclature of the species of the instant invention, which are 5H-2,3-benzodiazepine (species of claim 20) or 3,5-dihydro-5H-2,3-benzodiazepine (species of claim 5) are identical to the structures of Ling where the species disclosed are 5H-2,3-benzodiazepine

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or 4,5-dihydro-3H-2,3-benzodiazepine, respectively. What is being claimed is the chemical not the name.

Claims 1-19, 23-27 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Ling et al., WO 97/28135 (U.S. equivalent 6,200,970). For reasons of record and stated above.

6. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection of claims 16-19, 23-27 and 30 labeled paragraph 6 in the last office action which is hereby **withdrawn**.

7. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-30 labeled paragraph 7 of the last office action, the applicant's remarks have been fully considered but they are not persuasive. The applicants' stated that "the structure at p. 1 requires an un-saturation in the diazepine ring of the structure (represented by the dash line covering the 3-, 4- and 5-positions of the diazepine ring)" and "therefore, the generic structure of Ling does not encompass compounds which do not have an un-saturation in the 3-, 4-, and 5-positions of the diazepine ring". However, the disclosure of Ling is such that the dotted lines means a double bond or single bond which is clearly indicated by the species made.

The applicants' also stated that "claims 1-30 are drawn to 5H-2,3-benzodiazepine or 3,5-dihydro-5H-2,3-benzodiazepine compounds, compositions forming of the compounds or methods of using the compositions and/or compounds". However, as pointed out in the HCPLUS printout herein provided, the nomenclature of the species of the instant invention, which are 5H-

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2,3-benzodiazepine (species of claim 20) or 3,5-dihydro-5H-2,3-benzodiazepine (species of claim 5) are identical to the structures of Ling where the species disclosed are 5H-2,3-benzodiazepine or 4,5-dihydro-3H-2,3-benzodiazepine, respectively. What is being claimed is the chemical not the name.

Claims 1-19, 23-27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al., WO 97/28135 (U.S. equivalent 6,200,970). For reasons of record and stated above.

In view of the amendment dated March 20, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4, 8-12, 16, 23-25 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment with respect to the definition of R¹, R², R³ and R⁴ where R¹, R², R³ and R⁴ is R¹⁴S- is not described in the specification for the genus. The definition of R¹⁴ is such that R¹⁴ is H or C1-C3-alkyl.

Applicant is required to cancel the new matter in the reply to this Office action.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8-12, 16-19, 23-27 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1, 8, 9, 16, 23-25 and 30 are vague and indefinite in that it is not known what is meant by Halogen in the definition of R¹, R², R³ and R⁴ where halogen is capitalized.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim begins with a **capital letter** and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

- b) Claims 1-4, 8-12, 16-19, 23-27 and 30 are vague and indefinite in that it is not known what is meant by Halogen in the definition of R¹² where halogen is capitalized.
- c) Claims 2-4 are vague and indefinite in that it is not known what is meant by the definition of R⁹ which is not stated as a proper Markush grouping, i.e. R⁹ is

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.....R¹⁷OCO-, or R¹⁵CO- H. There is no "or" between the last two moieties and there is no comma separating the last two moieties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 8-10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Csuzdi et al., U.S. Patent No. 6,323,197. The generic structure of Csuzdi encompasses the instantly claimed compounds (see Formula I, column 1) and for the same uses as claimed herein. Examples 27, 28, 47-49, 54, etc. differ only in the nature of the A, X, Y, R¹, R², R³ and R⁴ substituents. Column 1, lines 33-63 defines the substituent R¹ and R² are the same or different and mean hydrogen, C₁₋₆ alkyl, nitro, halogen, cyano, the group -NR⁸R⁹, -O-C₁₋₄ alkyl, -CF₃, OH or C₁₋₆ alkanoyloxy; R³ and R⁴ are the same or different and mean hydrogen, halogen, C₁₋₆ alkoxy, hydroxy, thiocyanato, C₁-C₆ alkylthio, cyano, COOR¹², PO₃R¹³R¹⁴, C₁₋₆ alkanoyl, C₁₋₆ alkanoyloxy, C₂₋₆ alkynyl optionally substituted....., C₁₋₆ alkyl optionally substituted.....; X means hydrogen or halogen; Y means C₁₋₆ alkoxy or X and Y together mean -O-(CH₂)_n-O-; and A together with the nitrogen forms a saturated or unsaturated five-membered heterocycle, which can contain 1-3 nitrogen atoms and/or an oxygen atom and/or one or two carbonyl groups.

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Compounds of the instant invention are generically embraced by Csuzdi in view of the interchangeability of A, X, Y, R¹, R², R³ and R⁴ substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example A is -CH₂-O-CO- or -CH₂-NR³-CO- (from the preferred embodiments) as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brenda Coleman
Brenda Coleman
Primary Examiner AU 1624
May 23, 2003